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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,167

09/30/2003

Lloyd Marks

117622-00102

9810

27557

7590

04/04/2008

BLANK ROME LLP

600 NEW HAMPSHIRE AVENUE, N.W.

WASHINGTON, DC 20037

EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

04/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/673,167	<b>Applicant(s)</b> MARKS ET AL.	
	<b>Examiner</b> KAREN E. TOTH	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24,26,27 and 56-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24,26,27,56 and 57 is/are allowed.
- 6) ☒ Claim(s) 58-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***EXAMINER'S AMENDMENT***

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Edmonson on 20 March 2008.

The application has been amended as follows: Previously withdrawn claims 1-23 and 28-55 have been canceled, since they are not drawn to the elected invention.

### ***Claim Rejections - 35 USC § 103***

3. Claims 58, 59, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines (US Patent 6149587) in view of Arnold (US Patent Application Publication 2005/0107712).

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Raines discloses detecting a physical condition by taking quantitative pulse volume measurements at a plurality of positions on the patient's limbs (column 4, lines 43-49; column 6, lines 32-35; column 7 line 63 to column 8 line 5); and detecting the peripheral vascular disease from the quantitative pulse volume measurements (column 2 line 66 to column 3 line 14). Raines does not disclose calculating the area under the pulse volume curve to diagnose the physical condition. Arnold teaches calculating the area under a pulse volume curve to diagnose a physical condition (paragraphs [0022]-[0025]), in order to accurately identify the condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Raines and calculated the area under the pulse volume curve, as taught by Arnold, in order to accurately diagnose the physical condition.

Regarding claim 59, Raines further discloses that the measurements may be taken at different times and compared (column 6, lines 14-18) in order to determine the disease's current status (column 6, lines 1-3).

4. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Arnold, as applied to claims 58, 59, and 61 above, and further in view of Huizenga (US Patent Application Publication 2004/0043614).

Raines in view of Arnold discloses all the elements of the current invention, as described above, except for the method being performed both before and after a peripheral vascular disease treatment or stimulus in order to determine the efficacy of the treatment.

Huizenga teaches a method of detection of peripheral vascular disease where the vascular disease detection is performed both before and after treatment in order to determine the efficacy of the treatment (paragraphs [0023] and [0047]), so that a health care provider can determine if an alternate treatment is needed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Raines in view of Arnold and measured the patient's disease status both before and after treatment to determine the treatment's efficacy, as taught by Huizenga, so that a health care provider can determine if an alternate treatment is needed.

***Allowable Subject Matter***

5. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to anticipate or make obvious the method of claims 24, 26, 27, and 56-60, including, *inter-alia*, detecting peripheral vascular disease in a patient by calculating the area under a pulse volume curve (or integrating a pulse volume curve) for each of the patient's limbs, where the curves are obtained using signal averaging of quantitative pulse volume measurements that are taken at a plurality of positions on the patient's limbs.

Raines (US Patent 6149587) discloses a method for detecting peripheral vascular disease (that is, a physical condition) comprising taking quantitative pulse volume measurements at a plurality of positions on the patient's limbs (column 4, lines 43-49; column 6, lines 32-35; column 7 line 63 to column 8 line 5); and detecting the peripheral vascular disease from the quantitative pulse volume measurements (column

2 line 66 to column 3 line 14). Though Raines discloses measuring pulse volume, the area underneath the pulse volume curve is not measured or considered when performing diagnosis of disease, nor does Raines perform signal averaging of the pulse volume measurements.

Stephens (US Patent 3796213) teaches a method of diagnosing peripheral vascular disease by measuring pulse volume and performing signal averaging (column 2, lines 1-9) and then calculating pulse volume x heart rate (column 1, lines 14-19; column 2, lines 50-55). Stephens does not disclose calculating the area underneath the pulse volume curve.

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner, Art Unit 3735

/K. E. T./  
Examiner, Art Unit 3735